UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, SOUTHERN DIVISION

UNITED STATES OF AMERICA *ex rel.* DEBBIE BURKE	)	
	)	Civil Action No.
Plaintiff-Relator	)	FILED UNDER SEAL Pursuant to 31 U.S.C. § 3730
v.	)	
ST. JUDE MEDICAL, INC.	)	
Defendant	)	

COMPLAINT

Plaintiff/Relator Debbie Burke (Relator), by and through undersigned counsel, brings this False Claims Act Complaint, on behalf of the United States of America, against Defendant St. Jude Medical, Inc. (St. Jude or Defendant). This action is brought by Plaintiff/Relator to recover treble damages and civil penalties under the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*

INTRODUCTION

1. St. Jude knew as early as 2010 that implantable cardiac devices that it manufactured and sold had a potentially life threatening defect, that the batteries in certain devices were prone to premature battery depletion. This defect caused a patient death in 2014. In May of 2015, St. Jude took corrective manufacturing action to remedy the defect. Yet, despite this knowledge and action St. Jude continued to promote and sell devices it knew had defective batteries. St. Jude failed to inform physicians, patients, or

the Food and Drug Administration (FDA) that its devices had a potentially life threatening defect. Relator, Debbie Burke, received one of these defective devices 16 months after St. Jude remedied the defect.

NATURE OF ACTION

2. Relator brings this action on behalf of the United States to recover treble damages and civil penalties under the FCA.

3. Relator alleges that St. Jude violated the FCA by causing the submission of false or fraudulent claims to the Medicare program in violation of 31 U.S.C. § 3729(a)(1)(a).

4. Generally, no payments may be made under the Medicare program for expenses incurred for items or services that are not "reasonable and necessary" for the diagnosis and treatment of an illness. 42 U.S.C. § 1395y(a)(1)(A).

5. As early as 2010, and certainly no later than 2015, St. Jude knew that its Fortify, Unify, and Quadra lines of cardiac devices that it manufactured and sold had defective batteries that lead to premature battery depletion.

6. St. Jude did not take appropriate action to disclose the battery defect and the corrective manufacturing actions to the FDA or healthcare providers and continued to promote and sell the defective devices until they were recalled by the FDA on October 11, 2016.

7. St. Jude failed to reveal the battery defect to health care providers who may have had the defective devices on hand and continued to provide the defective devices to health care providers after it had knowledge of the defect.

8. At all times when comparable devices without battery defects were available, it was not reasonable and necessary for St. Jude's devices with the battery defect to be implanted in patients.

9. It was reasonable and foreseeable that St. Jude's defective devices would be implanted into Medicare patients.

10. As the direct, proximate, and foreseeable result of St. Jude's course of conduct, as set forth herein, St. Jude knowingly caused false or fraudulent claims to be submitted to the Medicare program for the implantation of defective cardiac devices.

JURISDICTION AND VENUE

11. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729-33. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and under the federal False Claims Act, 31 U.S.C. § 3732.

12. Venue lies in this district under 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a) because the Defendant transacts business and has violated 31 U.S.C. § 3729 in this district.

PARTIES

13. Relator brings this action on behalf of the United States and its agencies including the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS), which administer the Medicare program.

14. Relator is an adult citizen and resident of the State of Maryland. Relator is a recipient of one of St. Jude's defective devices. Specifically, on September 26, 2016 Relator received a Unify Assura cardiac device which was manufactured on May 12,

2015 with the known defective battery. The surgical implantation occurred in the State of Maryland at the Johns Hopkins Hospital located at 1800 Orleans Street, Baltimore, MD 21287.

15. Defendant, St. Jude is a Minnesota corporation, with its principal place of business and worldwide corporate headquarters located at One Street, Jude Medical Drive, St. Paul, Minnesota 55117. Upon information and belief, St. Jude's cardiac rhythm management division at all relevant times to this Complaint, developed, researched, advertised, promoted, marketed and sold all of St. Jude's implantable cardioverter defibrillators (ICDs), including the defective devices at issue herein. Upon information and belief, at all relevant times to this Complaint, St. Jude's cardiac rhythm management division's operations and manufacturing was principally conducted at its facilities located at 15900 Valley View Court, Sylmar, California 91342.

FALSE CLAIMS ACT

16. The federal False Claims Act (FCA) provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim to the Government is liable for damages in the amount of three times the amount of loss the Government sustained and penalties. 31 U.S.C. § 3729(a).

17. For false claims submitted prior to November 2, 2015 civil penalties under the FCA range between $5,500 and $11,000 per claim. 28 C.F.R. § 85.3. For false

claims submitted after November 2, 2015 civil penalties under the FCA range between $10,781 and $21,563 per claim. 28 C.F.R. § 85.5.

18. For purposes of the FCA, "the terms 'knowing' and 'knowingly' mean that a person, . . . (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). "[N]o proof of specific intent to defraud is required" for a successful claim under the FCA. *Id.*

THE FOOD, DRUG AND COSMETIC ACT

19. Implantable cardioverter defibrillators (ICDs) are classified as Class III medical devices under the federal Food, Drug and Cosmetic Act (FDCA) because they are used for "supporting or sustaining human life" and are "of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C)(ii)(I). Class III devices require pre-market approval from the FDA before they can be sold in the United States.

20. To obtain pre-market approval, a manufacturer must submit a pre-market approval application (PMA) to the FDA. 21 U.S.C. § 360e(c)(1). FDA regulations require that, after approval of a PMA, an applicant must "submit a PMA supplement for review and approval by the FDA before making a change affecting the safety or effectiveness of the devices for which the applicant has an approved PMA[.]" 21 C.F.R. § 814.39(a). According to the regulations, "changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: . . . (6) Changes in the performance or design

specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." *Id.*

21. The FDCA and FDA regulations require submission of a written report to the FDA within ten working days of initiating any "correction" of a device implemented to reduce a "risk to health" posed by the device. 21 U.S.C. § 360i(g); 21 C.F.R. § 806.10.

22. "Correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d).

23. "Risk to health means (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. § 806.2(j).

24. The removal or correction of a device that the agency considers to be in violation of the FDCA and against which the agency would initiate legal action is called a "recall." 21 C.F.R. § 7.3(g).

25. There are classes of FDA recalls, with Class III representing the least risk of possible health consequences and a Class I recall representing the most severe risk of possible health consequences. A Class I recall is defined as "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

THE MEDICARE PROGRAM

26. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, which is part of the Department of Health and Human Services. At all times relevant to this Complaint, CMS contracted with private contractors referred to as "fiscal intermediaries" and "carriers" to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

27. For inpatient treatment, reimbursement to treating facilities (such as hospitals) is governed by Medicare Part A, 42 U.S.C. §§ 1395c-1395i-5. For outpatient treatment, reimbursement to health care providers (such as doctors) is governed by Medicare Part B, 42 U.S.C. §§ 1395j-1395w-4.

28. To obtain Medicare reimbursement, providers submit claims using forms (known as CMS 1500s for outpatient claims and UB-92 or UB-04 for inpatient treatment). Providers identify by code on the appropriate form, among other things, the principal diagnosis of the patient and the procedures and services rendered.

29. Under the Medicare program, "no payment may be made under part A or part B for any expenses incurred for items or services which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs)

30. This case involves St. Jude's lines of implantable cardiac devices: Fortify, Unify, and Quadra lines. These products are cardiac defibrillators, which are designed to prevent sudden cardiac death by detecting and treating ventricular tachycardia and ventricular fibrillation. If the devices detect tachycardia or fibrillation, they emit an electrical pulse to deliver potentially life-saving "shock" to the heart to return to normal rhythm.

31. More specifically, an ICD is an implantable medical device that is used to correct heart arrhythmia (abnormal heart rhythm). The device is surgically implanted in the patient's chest cavity and connected to the patient's heart by electrical wires called "leads." The "header" of the device is a formed plastic cap that channels wires from the device's metallic pulse generator, which contains the battery, to a port where the wires are connected to the leads. The "feedthrough wire," located within the header, is designed to carry the electrical charge from the pulse generator to the leads. Implantable cardiac resynchronization therapy defibrillators (CRT-Ds) are ICDs with an additional function that enables the heart to pump more efficiently.

32. "Interrogation" describes the evaluation of an ICD and the retrieval of stored information from the device. An interrogation assesses various factors that could affect the performance of the ICD, such as whether the leads or pulse generator are functioning normally, the status of the battery, and whether an abnormal heart rhythm has been detected by the ICD.

33. Patients who are treated with ICDs include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat), or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death, unless the device delivers the proper therapy to put the patient's heart back into a normal cardiac rhythm.

34. Once implanted, a properly functioning ICD or CRT-D continuously monitors the patient's heartbeat for irregular rhythms. If tachycardia is detected, the device will generate a series of timed, electrical pulses delivered to the heart along the leads to reset the heart to normal rhythm. Similarly, when ventricular fibrillation is detected, the device will deliver sudden shocks along the leads to the heart to stop the potentially-fatal heart quivering.

35. ICDs and CRT-Ds are battery powered and therefore have a shelf life. When the battery in the device is nearing the end of its power supply, the device gives an alert called an Elective Replacement Indicator (ERI) alert. Typically when a patient receives an ERI alert, they have 3-months of power supply left. In other words the device alerts the patient that they have 3 months to replace the device.

FACTUAL ALLEGATIONS

FDA Recall

36. On October 11, 2016 the FDA issued a Class I recall regarding St. Jude's line of Fortify, Unify, and Assura ICDs and CRT-Ds. The full list of the recalled devices are:

a. Fortify VR: Model No(s). CD1231-40, CD1231-40Q;

b. Fortify ST VR: Model No(s). CD1241-40, CD1241-40Q;

c. Fortify Assura VR: Model No(s). CD1257-40, CD1257-40Q, CD1357-40C, CD1357-40Q;

d. Fortify Assura ST VR: Model No(s). CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q;

e. Fortify DR: Model No(s). CD2231-40, CD2231-40Q;

f. Fortify ST DR: Model No(s). CD2241-40, CD-2241-40Q, CD2263-40, CD2263-40Q;

g. Fortify Assura DR: Model No(s). CD2257-40, CD2257-40Q, CD2357-40C, CD2357-40Q;

h. Fortify Assura ST DR: Model No(s). CD2363-40C, CD2363-40Q;

i. Unify: Model No(s). CD3231-40, CD3231-40Q;

j. Unify Quadra: Model No(s). CD3249-40, CD3249-40Q;

k. Unify Assura: Model No(s). CD3257-40, CD3257-40Q, CD3357-40C, CD3357-40Q;

l. Quadra Assura: Model No(s). CD3265-40, CD3265-40Q, CD3365-40C, CD3365-40Q;

m. Quadra Assura MP: Model No(s). CD3269-40, CD3269-40Q, CD3369-40C.

37. The FDA stated the purpose of the recall was that the batteries on these devices may fail earlier than expected and that due to the problems with the batteries, the

battery may fail and run out within 24 hours of the patient receiving an ERI alert, instead of the normal 3 month lead time.

38. The FDA went on to explain in the October 11, 2016 recall that the cause of the rapid battery depletion was lithium deposits, called lithium clusters, which formed within the battery and created abnormal connections which rapidly drained the battery.

39. Included in the FDA recall notice was a number of recommendations to health care providers, including:

a. Do not implant affected devices;

b. Pacemaker-dependent patients with a device that has reached ERI should be treated as a medical emergency.

40. St. Jude itself issued a medical advisory stating that "after an analysis found that some devices manufactured prior to May 23, 2015 contain batteries which may run out of energy earlier than expected. This is termed 'premature battery depletion.'"

Relator's CRT-D Device

41. On September 26, 2016, the Relator was surgically implanted with a St. Jude CRT-D device. The particular device she received was a Unify Assure, model number CD3357-40C, serial number 7205314. This device was manufactured on May 12, 2015 and is one of the recalled devices based on the date of manufacturing. This can be confirmed by the model number and serial number of Relator's device through St. Jude's online medical advisory regarding the FDA recall.

42. The Relator is pacemaker dependent and the September 26th surgery was a device replacement surgery because her prior device had reached ERI and was

approaching battery depletion. The prior device was implanted in 2010. She has been pacemaker dependent since 2005, and is on her third CRT-D device.

43. The Relator's surgeon, Dr. Sunil Sinha, performed the implantation and explantation surgery which occurred on September 26, 2016. Relator has treated at Johns Hopkins Hospital since her first CRT-D implantation surgery in 2005.

44. Within two weeks of the implantation surgery, the FDA issued the recall for the multiple lines of St. Jude's ICD devices, including Relator's. Relator was rightfully concerned as she is pacemaker dependent. Relator's doctor, Dr. Sunil, was unaware of any issues regarding the batteries of St. Jude's ICD devices prior to the FDA recall.

45. A St. Jude sales representative was present at Relator's September 26, 2016 implantation surgery. The St. Jude representative provided the Unify Assure CRT-D device for implantation that day. In other words, Dr. Sunil and Johns Hopkins Hospital does not keep an inventory, or pre-purchase in bulk ICD devices. They are provided by the manufacturer representative as needed.

46. St. Jude directly provided the defective device to Relator's surgeon, a device which the company definitively knew was defective at the time of Relator's implantation surgery. Further, St. Jude knew for years that its ICD devices had a defective battery which could lead to battery depletion as further described below.

St. Jude's Knowledge of its Defective ICD Devices

47. St. Jude knew as early as 2010 that its ICD devices had a life threatening battery defect which could lead to premature battery depletion and continued to market, promote, and sell these devices.

48. First, on May 23, 2015 St. Jude took corrective action regarding the defective batteries. Devices manufactured after that date do not contain the defect of "lithium clusters" which lead to premature battery depletion. St. Jude knew of and appreciated the danger its ICD devices presented to patients and took the affirmative steps to changing the battery manufacturing process in order to correct the defect.

49. The change was intended to affect both the safety and efficacy of the ICD devices. It was implemented for the purpose of correcting a known defect that could leave the device inoperable. St. Jude is required to submit PMA supplement if the change in manufacturing would affect the safety and efficacy of the device.

50. Even if St. Jude had filed the appropriate FDA PMA supplement, they nevertheless continued to promote, market, and sell the Fortify, Unify, or Assura lines of ICDs that had been manufactured prior to May 23, 2015 that contained the battery defect.

51. Further, St. Jude sent no advisory to health care providers at that point warning of the possible defect and that it had taken corrective action to ensure that future ICD devices were not defective. As stated herein, Relator's surgeon knew nothing of the battery defect until the FDA issued its recall in October of 2016.

52. But St. Jude obviously knew well before 2015 and its corrective action that its batteries in its ICD devices were defective. In December 2014, in an attempt to

explain the unexpected battery failure they had observed in St. Jude ICD devices, several doctors from the Duke University Medical Center published a study entitled "Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter-defibrillators."[1]

53. The stated objective of the study was "to describe the prevalence of a novel mechanism of battery failure in St. Jude Medical Fortify and Unify ICDs." The conclusion reached by the study was "[t]he deposition of lithium clusters near the cathode is a novel mechanism of premature battery failure."

54. The study's conclusion is identical to the cause given by the FDA in its recall some 22 months later. Yet, St. Jude continued to promote, market, and sell its ICD devices with this known defect.

55. Further, cases of premature battery failure from St. Jude's ICD devices can be searched through the Food and Drug Administration's Manufacturer and User Facility Device Experience Database (MAUDE). MAUDE houses medical device reports submitted to the FDA by mandatory reporters. According to the FDA, manufacturers must "submit reports when they become aware of information that reasonably suggest that one of their marketed devices may have caused or contributed to a death or serious injury or has malfunctioned and the malfunction of the device or a similar device that

[1] Sean D. Pokorney, Ruth Ann Greenfield, Brett D. Atwater, James P. Daubert, Jonathan P. Piccini, *Novel mechanism of premature batter failure due to lithium cluster formation in implantable cardioverter-defibrillators,* Vol. 11, Issue 12, Heart Rhythm, 2190, (Dec. 2014).

they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." A search of this database reveals the following:

a. On June 27, 2014 a death was reported where a St. Jude Unify CRT-D failed because of premature battery depletion.

b. When searching the St. Jude Fortify line of ICDs, MAUDE reveals that there are 500 reports regarding premature battery depletion between the dates of February 27, 2014 and June 27, 2016. Those dates are insignificant but for the MAUDE database can only respond with a maximum of 500 results when queried. There were an additional 53 reports for the year 2013. The earliest Fortify medical device report according to the MAUDE database is May 12, 2011 where an injury resulted from a reported premature battery depletion.

c. When searching the St. Jude Fortify line of ICDs, MAUDE reveals that there are 324 device medical reports between the dates of June 8, 2015 and June 27, 2016. All of which are following the May 23, 2015 corrective action date and before the FDA recall.

d. When searching the St. Jude Unify line of ICDs, MAUDE reveals that there were 236 device medical reports between the dates of November 10, 2010 and June 19, 2016. It further reveals 113 medical device reports between the dates of June 3, 2015 and June 19, 2016. Again, those 113 reports are dated following the May 23, 2015 corrective action taken by St. Jude and before the FDA recall.

e. When specifically searching the name Unify Assura, the ICD device in which Relator received, MAUDE reveals 23 device medical reports between June 30, 2013 and June 16, 2016.

56. After St. Jude took corrective action in May of 2015, the FDA continued to receive device medical reports regarding premature battery depletion in St. Jude's ICDs.

57. Despite taking the corrective action to rectify a known defect with the batteries in its ICDs, St. Jude continued to promote, market, and sell the defective ICDs which were implanted in patients, including the Relator.

58. Following the corrective action, St. Jude did not notify any health care providers that ICDs manufactured prior to May of 2015 were defective and continued to sell the defective devices until the FDA issued a recall in October of 2016 for those devices.

Medicare Payments for ICD Devices

59. Although the Relator is not a Medicare beneficiary, it is reasonably foreseeable that Medicare paid for the defective versions of St. Jude's ICD devices.

60. According to the Journal of Internal Medicine, published in 2007, Medicare was, by percentage, the largest payor for cardiac device implantations in the year 2004. Medicare paid for 73% of CRT-D implantations and 82% of pacemaker implantations.

61. Further, St. Jude in its 2015 annual report states that "[o]ur products are purchased principally by healthcare providers that typically bill various third-party payors, such as governmental programs, private insurance plans and managed care

plans…." The report continues "[o]ur hospital customers rely heavily on Medicare and Medicaid programs to fund their operations. Any cuts to these programs could negatively affect the business of our customers and our business."

62. In 2015, St. Jude reported that net sales of ICD systems totaled $1.582 billion. Which was a 9.4% decrease from ICD sales in 2014 which totaled $1.746 billion. Total net sales for the company in 2015 worldwide was $5.541 billion, with $2.838 billion of net sales occurring in the United States.

False Claims

63. The implantation of the St. Jude ICD devices which had the defective lithium batteries when non-defective devices were available was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

64. St. Jude began receiving medical device reports notifying them of the battery defect as early as 2010, but continued to market, promote and sell the defective ICD devices even after it took corrective manufacturing action to remedy the defect.

65. St. Jude took corrective action on May 23, 2015, but failed to notify the health care providers of the battery change, and continued to market, promote and sell the defective ICD devices. The Relator received a defective St. Jude ICD device 16 months following the May 23, 2015 correction.

66. As a result of its fraudulent course of conduct, St. Jude knowingly caused the submission of false or fraudulent claims for implants of defective and faulty Fortify, Unify, and Assura ICD devices to the Medicare Program. These false and fraudulent

claims were not eligible for payment because the services were not "reasonable and necessary for the diagnosis or treatment of illness or injury…" 42 U.S.C. § 1395y(a)(1)(A).

COUNT I
FALSE CLAIMS ACT VIOLATIONS
31 U.S.C. § 3729(a)(1)(A)
(Presenting or Causing Presentment of a False Claim)

67. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint

68. By virtue of the acts described above, St. Jude knowingly caused to be presented, false or fraudulent claims to the United States Government for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(a).

69. By virtue of the false or fraudulent claims that St. Jude caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties for each violation.

PRAYER FOR RELIEF

WHEREFORE, the Relator on behalf of the United States demands and prays that judgment be entered in its favor against St. Jude as follows:

1. On the First Count under the False Claims Act, treble damages as required by law, and such civil penalties as are required by law, together with all such other further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, the United States of America, on relation of Plaintiff-Relator Debbie Burke, hereby demand trial by jury on all issues so triable.

Respectfully submitted,

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